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TRANSMITTAL FORM

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Total Number of Pages in This Submission: 5

Application Number	09/815,573
Filing Date	March 22, 2001
First Named Inventor	Hector F. DeLuca
Art Unit	1617
Examiner Name	Shaojia A. Hiang
Attorney Docket Number	1256-00721

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Andrus, Sceales, Starke & Sawall, LLP		
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Date	07/01/2005	Reg. No.	28,922

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Signature	Jo Ann Kuczynski		
Typed or printed name	Jo Ann Kuczynski	Date	07/01/2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	09/815,573
Applicant	:	Hector F. DeLuca et al
Filed	:	March 22, 2001
Title	:	Increasing Phosphorus Uptake from the Gut of Dairy Cows by Supplementing 1α-Hydroxylated Vitamin D Compounds
TC/A.U.	:	1617
Examiner	:	Shaojia A. Jiang
Docket No.	:	1256-00721

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JoAnn Kuczynski 7-1-05
Jo Ann Kuczynski Date

RESPONSE TO OFFICE ACTION

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Patent Office Action dated April 1, 2005, please enter the following in the above-identified application:

In the Office Action dated April 1, 2005, claims 8-14 were examined with the result that all claims were rejected. In response, applicant submits the following comments. In view of these comments, reconsideration of claims 8-14 is herein requested.

In the Office Action, claims 8-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al. WO 96/24258. The Examiner states that the '258 reference describes a method of improving utilization of phytate phosphorus so as to reduce or minimize or perhaps eliminate dietary requirements of phosphorus in animals, including dairy cows. In view of this teaching, the Examiner believes that it would be

obvious to one of ordinary skill in the art to replace all inorganic phosphorus in a diet with an effective amount of a 1α-hydroxylated vitamin D compound, as claimed by applicant. Applicant, however, respectfully disagrees for the following reasons.

As discussed in applicant's specification, much of the phosphorus in plant foods and feeds passes through the GI tract of an animal and is excreted in the animal's feces. In animal husbandry, which includes diary cows, this is accounted for in diet formulation by providing an inorganic phosphorous source in a feed supplement which is added to the normal diet of an animal to meet the animal's minimum phosphorus requirements. Since supplemental inorganic phosphorous is a relatively expensive ingredient in an animal's diet, its reduction and/or elimination would be desirable from a cost standpoint. However, with regard to dairy cows, such reduction and/or elimination of inorganic phosphorous cannot be made at the expense of milk yields. If milk yields in dairy cows were reduced due to the elimination of supplemental quantities of phosphorous, owners of dairy cow herds would never incorporate or utilize such a diet. Thus, any diet which eliminates inorganic phosphorous supplements must ensure that milk yields do not decline.

In the past, one skilled in the art would not have fed a low phosphorous diet to an animal such as dairy cows because it would have readily been recognized that a feed supplement without any phosphorous in the cow's diet would not have met the minimum phosphorous requirements for the animal. It is recognized by all those skilled in the art that lactating dairy cows require sufficient P in their diets in order to maintain adequate milk yields. Typically, a normal diet for dairy cows contains about 0.9% phosphorous. Thus, applicant's claim 1 which calls for replacing all inorganic phosphorous in a diet for a dairy cow with a vitamin D compound is clearly in contrast to conventional thinking, and one skilled in the art would not readily accept that all inorganic phosphorous supplements could be eliminated while still maintaining high milk yields in dairy cows. Such a concept is simply contrary to what would be accepted by one skilled in the art.

There is simply no suggestion in WO 96/24258 that one could replace all inorganic phosphorous in a diet for lactating dairy cows and still maintain high milk yields in dairy

cows, especially when one considers the abnormally low phosphorous content of the dairy cow's diet. What the '258 reference does teach is that the incorporation of a 1α-hydroxylated vitamin D compound in an animal's diet will increase utilization of phytate phosphorous, and as a result, one can replace supplemental phosphorous with additional grain which would therefore increase the useable energy in the diet of the animal. It would also reduce the phosphorous excreted in the animal's feces to reduce the polluting effects of P on the environment. However, there is nothing in the '258 reference which teaches or suggests that one can replace all inorganic phosphorous supplements in a lactating dairy cow's diet and still maintain high milk yields. Thus, what one skilled in the art learns from the '258 reference is that by incorporating a 1α-hydroxylated vitamin D compound in the diet of an animal, one can increase utilization of phosphorous from phytate complexes in the diet which in turn enables the removal of unneeded supplemental quantities of P and substitution with grain to increase the useable energy in the animal's diet (and decrease P in the animal's feces). However, there is no disclosure relating to milk yields.

Applicant admits that the '258 reference refers to the possibility of minimizing or perhaps eliminating the need for supplemental quantities of P in an animal diet by the incorporation of a 1α-hydroxylated vitamin D compound in the animal's diet. However, the '258 reference does so only in the context of replacing that inorganic P with additional grain to increase the useable energy in the animal's diet. The '258 reference never refers to replacing all of the inorganic phosphorous in the diet of a lactating dairy cow because it was always presumed that such a substitution would reduce milk yields due to the fact that dairy cows require relatively high amounts of P in their diets in order to maintain adequate milk yields. Thus, replacing all of the inorganic P in the diet of a lactating cow is unexpected to one skilled in this art.

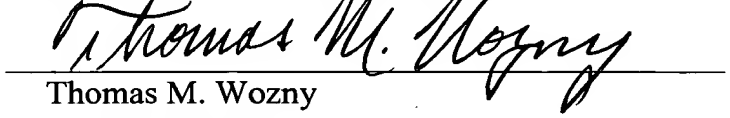
The Examiner indicates that the data in the specification is expected rather than unexpected. However, one skilled in the art clearly would not feed a diet to an animal which would not meet what is considered to be the minimum P requirements for that animal. In this case, about 0.9% P is accepted by those skilled in the art for dairy cows.

Thus, one skilled in the art would expect that a diet containing less than about 0.9% P would not be sufficient to provide adequate nutrition for the dairy cow. Therefore, why would one skilled in the art feed a diet containing 0% inorganic P supplement when the normal amount is 0.9%, and especially when knowing that 0.9% has been thought to be the required amount to provide the minimum P requirements for dairy cows? As stated in applicant's specification, a reduction of inorganic P cannot be made at the expense of milk yields. The data found in applicant's specification shows that even though the diet contained low P, milk production and high milk yields were maintained. To one skilled in the art, this is an unexpected result since it was presumed in the past that one needed to feed at least about 0.9% P to maintain milk production and adequate milk yields. The feeding of such low P levels, with the result that milk production and yield is maintained, is clearly an unexpected result which would not have been predicted by one skilled in the art in view of the conventionally accepted requirement of feeding at least about 0.9% P to dairy cows.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By 

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